

K 960302
ATTACHMENT 8

**Summary of Safety and Effectiveness
510(k) SUMMARY**

APR - 1 1996

**US MEDICAL PRODUCTS, INC.
CONSENSUS® Acetabular Shell, All UHMWPE**

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Trade Name: Consensus® Acetabular Shell, All UHMWPE

Common Name: Hip replacement prosthesis, Acetabular Shell, All UHMWPE

Classification Name: Class II device, under the following classification:

Prosthesis, Hip, Semi-Constrained Metal/ Polymer
classification 21 CFR 888.3350

Substantial Equivalence: equivalent Acetabular Shell, All UHMWPE components are as follows:

Howmedica Acetabular Shell, All UHMWPE K912426 SE 8-21-91

Device Description: The Consensus® Acetabular Shell, All UHMWPE is intended for use with the Consensus® Total Hip System as an alternative to the the metal acetabular shell and UHMWPE acetabular insert components in the Consensus® Total Hip System. It is a single use device. The Consensus® Acetabular Shell, All UHMWPE is designed for use with size compatible Consensus® Total Hip System components:

Femoral Head, BioloX Ceramic	K922561	SE 07-21-93
Femoral Head, Zirconia	K955386	SE 11/06/95
Femoral Head, CoCrMo	K922561	SE 07-21-93

The 22mm diameter, 26mm diameter, and 28mm Shells are intended to be used with compatible diameter femoral head components.

The Concensus® Acetabular Shell, All UHMWPE will be provided sterile and will be available in fourteen sizes for 22mm heads (42mm to 68mm in 2mm increments), in twelve sizes for 26mm heads (46mm to 68mm in 2mm increments), and in eleven sizes for 28mm heads (48-68mm in 2mm increments). The material will be ultra high molecular weight polyethylene (UHMWPE), ASTM F648.

Intended Use: The CONSENSUS® Acetabular Shell, All UHMWPE is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis and avascular necrosis with a non-acute fracture of the femoral neck.
2. Osteoarthrosis involving femoral and acetabular articular surfaces.
3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. Fracture-dislocation of the hip.
5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

Summary of Technological Characteristics: The Concensus® Acetabular Shell, All UHMWPE, is designed to articulate with the various Concensus® Hip femoral head components. The Concensus® Acetabular Shell, All UHMWPE, will be provided sterile and will be available in fourteen sizes for 22mm heads (42mm to 68mm in 2mm increments), in twelve sizes for 26mm heads (46mm to 68mm in 2mm increments), and in eleven sizes for 28mm heads (48-68mm in 2mm increments). The material will be ultra high molecular weight polyethylene (UHMWPE), ASTM F648.

Performance Data: The Concensus® Acetabular Shell, All UHMWPE, device performs with substantial equivalence to predicate devices.

Clinical Data: None Required

Conclusions from Non-clinical and Clinical Data: The Concensus® Acetabular Shell, All UHMWPE, is substantially equivalent to predicate devices.

Other Necessary Information: None Required